UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

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IN RE: DIGITEK® PRODUCTS LIABILITY LITIGATION : MDL NO. 1968

(This document relates to all cases.)

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CONFIDENTIAL - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

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New York, New York
Tuesday, December 15, 2009

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Videotaped Deposition of SWAPAN ROYCHOWDHURY, held at Harris Beach PLLC, 100 Wall Street, 24th Floor, on the above date, beginning at 9:44 a.m., before Kimberly A. Overwise, a Certified Realtime Reporter and Notary Public.

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GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

APPEARANCES:

MOTLEY RICE, LLC
BY: FRED THOMPSON III, ESQ.
MEGHAN JOHNSON CARTER, ESQ.
28 Bridgeside Boulevard
Mt. Pleasant, SC 29464
843-216-9118
fthompson@motleyrice.com
mjohnson@motleyrice.com
Counsel for MDL Plaintiffs' Steering Committee

THE MILLER FIRM LLC
BY: PETER A. MILLER, ESQ.
The Sherman Building
108 Railroad Avenue
Orange, VA 22960
540-672-4224
pmiller@doctoratlaw.com
Counsel for Pennsylvania Plaintiffs

BLIZZARD, McCARTHY & NABERS, LLP
BY: SOFIA BRUERA, ESQ.
Lyric Centre Building
440 Louisiana, Suite 1710
Houston, TX 77002-1689
713-844-3750
sbruera@blizzardlaw.com
Counsel for Plaintiffs

SANFORD BARLOW, LLP
BY: SHELLY A. SANFORD, ESQ.
1500 McGowen, Suite 250
Houston, TX 77004
877-441-6677
ssanford@sanfordbarlow.com
Counsel for Plaintiffs and Plaintiffs' Steering Committee

APPEARANCES: (Continued)

TUCKER ELLIS & WEST LLP
BY: MICHAEL ANDERTON, ESQ.
JOHN A. SIMON, ESQ.
1150 Huntington Building
925 Euclid Avenue
Cleveland, OH 44115-1414
216-696-2276
michael.anderton@tuckerellis.com
john.simon@tuckerellis.com
Counsel for Actavis Defendants

SHOOK, HARDY & BACON, LLP
BY: HUNTER K. AHERN, ESQ.
JPMorgan Chase Tower
600 Travis Street, Suite 1600
Houston, TX 77002-2992
713-227-8008
hahern@shb.com
Counsel for Mylan Defendants

ALLEN GUTHRIE & THOMAS, PLLC
BY: ZACKARY B. MAZEY, ESQ.
500 Lee Street, East, Suite 800
Charleston, WV 25301
304-720-4226
zbmazey@agmtlaw.com
Counsel for West Virginia Actavis Defendants

ALSO PRESENT:

Catherine Smalfus, videographer
Golkow Technologies, Inc.

all testing of all finished product; is that correct?

A That's correct.

Q You were also responsible for the training of analysts during that time period, sir?

A That's correct.

Q And you were responsible for the evaluation of data and the assurance that all instruments were qualified?

A That's correct.

Q Calibrated?

A That's correct.

Q And maintained?

A That's correct.

Q That's quite a responsibility, is it not, sir?

A That's correct.

Q What did you do to ensure in that time frame that all raw materials and finished product were tested appropriately?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: We have all the

procedures for all these raw materials how to test, all the finished product, all in-process material; and the chemists were trained, and they followed the procedures and tested the product accordingly.

BY MS. SANFORD:

Q Sir, how many employees did you have in the time period from April of 2007 when you began at Actavis up to May of 2008?

A I was managing a group of about 50 people.

Q Okay. And in what departments were those people?

A Quality control laboratory.

Q And where were they located, sir?

A In Little Falls --

Q And you were --

A -- till December of 2008.

Q So you had approximately 50 people at the Little Falls facility in the time period between January -- April 2007 and December 2008 that were under your direct control?

A I have --

MR. ANDERTON: Objection.

Wait for me to determine whether I need to object to the question, please.

BY MS. SANFORD:

Q Sir, and production was behind as well in that time period, was it not?

MR. ANDERTON: Objection.

THE WITNESS: I have no idea.

BY MS. SANFORD:

Q You have no idea?

A I don't know.

Q Okay. You never saw the documents that showed whether something was in a back order or backlog situation at all?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I don't remember.

BY MS. SANFORD:

Q You were never asked to rush through the quality control so they could get products out the door?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Yeah, we have requests. And we properly test and review the documents and appropriately release the product.

BY MS. SANFORD:

Q So, sir, you understand there's always a tension to try and get the product out the door as quick as possible; isn't that true, sir?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I never felt any inappropriate pressure to release the product out the door.

BY MS. SANFORD:

Q Whether or not it's inappropriate, sir, you felt some pressure to get the product out the door; isn't that true?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: We have a request if we can test the product in time.

BY MS. SANFORD:

Q And that's pretty common in your industry, is it not, sir?

A That's expected.

Q And, in fact, there was a backlog on requests for production of the drugs that were being manufactured; is that not true, sir?

MR. ANDERTON: Objection; asked and answered.

THE WITNESS: I don't know any backlog about production situation.

BY MS. SANFORD:

Q So as part of the senior -- being a senior official at Actavis in that time frame, you were never told about backlogs or backorders on documents --

MR. ANDERTON: Objection.

BY MS. SANFORD:

Q -- on drugs? I'm sorry.

MR. ANDERTON: I'm sorry.

Objection; asked and answered.

THE WITNESS: I don't remember.

BY MS. SANFORD:

Q You can't remember whether you were

told, or you don't remember if you were ever told?

A I don't remember I was ever told that we have backlog.

Q But you knew there were backlogs, did you not, sir?

MR. ANDERTON: Objection; asked and answered.

THE WITNESS: I don't know.

BY MS. SANFORD:

Q If there are documents in your file that show there were backlogs that were maintained in your personal file, would you agree that you at least saw them at some point in time?

MR. ANDERTON: Objection. Are you asking him about a document or --

MS. SANFORD: No. I'm asking him the question I asked.

MR. ANDERTON: Okay.

THE WITNESS: I have to see the document.

BY MS. SANFORD:

Q So if it's part of your file, then

Q And he made no comment to you about how or why he left the company?

MR. ANDERTON: Objection; asked and answered.

THE WITNESS: I didn't have any other discussion with him.

BY MS. SANFORD:

Q As far as Ms. Lambridis is concerned, sir, someone else testified that Ms. Lambridis left so her name would not be on the consent decree. Do you have any reason to dispute that?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I don't know.

BY MS. SANFORD:

Q You know what the consent decree is, sir?

A Yes.

Q Can you explain to the jury what that is?

MR. ANDERTON: Objection.

THE WITNESS: That's a legal document between Actavis, the party, and

USFDA and the procedures and actions they will take to remedy it, the situation.

BY MS. SANFORD:

Q And the situation was what, sir, to your understanding?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Situation that was discussed between both the parties.

BY MS. SANFORD:

Q Okay. Can you describe that more specifically? What was it about?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: To improve certain procedures, practices, and how to go about others and the time frame.

BY MS. SANFORD:

Q And improving, sir, improving certain procedures and practices of the company in the time frame in which that had to be done involved your department, did it not?

A Repeat that again.

Q Improvement in certain procedures

involved your department directly, did it not, sir?

A It involves the entire company.

Q But the need for improvement in certain areas and procedures that you just described specifically involved your department, did it not, sir?

A When we need to improve on -- I mean, there is always an opportunity to improve on the procedure. And if it falls in our department, we improve those procedures.

Q And I'm asking a little bit of a different question, sir. I'm saying that, in fact, it did involve your department, the need to have improvements in certain procedures; is that correct?

MR. ANDERTON: Are you talking about the analytical services department when you say "your department"?

BY MS. SANFORD:

Q Sir, do you understand my question?

A Could you rephrase that, please? Does it involve analytical service?

MS. SANFORD: If you have an

analytical services; is that what you're trying to do?

A From April of 2008, I was in analytical service.

Q From April of 2008?

A '8.

Q You understand the consent decree, sir, dealt with conduct of the company all through 2007 as well; correct?

A That's -- okay.

Q Do you know that, sir?

A Yes.

Q And the need for improvement in certain procedures dealt with the department that you were director of, sir, in that time frame; is that correct?

A That's right.

Q And specifically in the area of quality control, there were numerous failures that were cited in that department, sir; isn't that correct?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Could you be more

specific about that failure that you're talking about?

BY MS. SANFORD:

Q What time period I'm talking about?

A The failure you're talking about.

Q Well, I'm asking you, sir, if you know that there were failures addressed in the area of quality control that were the subject of the consent decree.

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Well, unless you show me some failures, I really don't remember.

BY MS. SANFORD:

Q Well, it's not your testimony, sir, that the quality control department was perfect in that time frame, is it?

MR. ANDERTON: Objection.

THE WITNESS: Well, nobody --

MR. ANDERTON: You may answer.

THE WITNESS: Nobody claimed they are perfect. We always want to improve because it's a changing

environment. Pharmaceutical industry is a changing environment.

BY MS. SANFORD:

Q And, sir -- I'm sorry. Are you finished?

A Yeah.

Q I don't mean to step on you with your answers. But, sir, the consent decree, you will admit, shut your company down?

MR. ANDERTON: Objection.

BY MS. SANFORD:

Q Correct?

MR. ANDERTON: You may answer.

THE WITNESS: Consent decree is not to shut you down. It's a legal binding between both the parties how to rectify the procedures and what time frame, and all the procedures are in detail in that document.

BY MS. SANFORD:

Q Well, I'm not talking about a theoretical consent decree. I'm talking about the actual consent decree that was signed between Actavis and the Department of Justice

management meetings with FDA that occurred?
A No.
Q Were you invited to any of those meetings?
A No.
Q Were you told about the results of any of those meetings?
A To FDA?
Q Yes. Senior management meeting with the FDA --
A No.
Q -- did anybody tell you about those meetings, about what happened in them --
A No.
Q -- or what was decided?
A No.
Q Your input was not requested at all?
A No.
Q What was -- do you remember any of the questions that were asked by the FDA officials when they came to investigate --
MR. ANDERTON: Objection.
BY MS. SANFORD:
Q -- in 2008?

MR. ANDERTON: Objection. I'm going to instruct you to answer only with respect to Digitek.

THE WITNESS: Can you rephrase your question?

BY MS. SANFORD:

Q Do you remember any of the questions that were asked of you when the FDA came to visit in 2008?

MR. ANDERTON: And I'm going to again instruct you to limit your answer to Digitek, please.

THE WITNESS: No. FDA didn't ask me any question regarding Digitek.

BY MS. SANFORD:

Q Did they ask you questions regarding other drugs?

MR. ANDERTON: Objection.

Wait.

You may answer. But in answering, again, I instruct you not to give any substantive response other than -- so don't identify the drugs. You may answer her question generally.

THE WITNESS: FDA had some specific clarification they need on certain issues, and I explained those issues.

MS. SANFORD: Can you read back my question.

(The court reporter read the record as follows:

"QUESTION: Did they ask you questions regarding other drugs?")

BY MS. SANFORD:

Q Can you answer that question, sir?

A Yes.

Q The answer is yes?

A Other drugs, yes.

Q And it's your position that there were no questions asked of you, at least, in that time frame about Digitek at all?

A I didn't respond anything to FDA regarding Digitek.

Q Were you asked any questions by the FDA regarding Digitek?

A No.

Q Did you provide any documents to the

FDA to review regarding Digitek?

A I have provided all my laboratory investigation to our quality group; and they, in turn, provided all this to FDA. So I don't know what is involved in that.

Q In regard to the other drugs, sir, without naming the drugs, was it related to out-of-specification documents that they asked you questions?

MR. ANDERTON: Objection.

Give me a second.

You may answer.

THE WITNESS: Could you rephrase your question?

BY MS. SANFORD:

Q In regard to the other drugs, sir, was it regard to out-of-specification documents that you were asked questions by the FDA?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: They have specific question regarding one of my investigation, and I explained the

investigation outcome.

BY MS. SANFORD:

Q And did that -- did those specific questions relate to the drug being out of specification?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: "Investigation" not necessarily mean out of specification. "Investigation" means we do investigation if we observe some aberrant data, out of specs, number of issues. So without knowing the specific, I cannot answer that.

BY MS. SANFORD:

Q You can't remember, as you sit here today, whether it involved the drug being out of specification? And by "it," I mean the questions of the FDA.

A I don't understand your question.

Q The FDA asked you about a specific investigation. You just said that; is that correct?

A (Witness shakes head.)

Q Okay. Did that investigation involve the drug being out of specification?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I don't recall whether it's a specific out-of-specification issue.

BY MS. SANFORD:

Q You just can't remember as you sit here today?

A I don't remember.

Q Was it only one time that you were asked questions by someone from the FDA?

A Twice I appeared in front of FDA.

Q And when you twice appeared in front of the FDA, you just -- did you go into a meeting? How did that happen? Did you go to a meeting room, or did they come to you? Just tell me the specifics.

A They were in one conference room. They have -- they had at that time my investigation, and they had a specific question. And I went there and explained the situation, my findings.

A Yeah.
Q Paragraph 11 begins by saying: "FDA's five inspections of Actavis Totowa's facilities over the last three years have revealed numerous and recurring violations of the current Good Manufacturing Practice (CGMP) requirements for drugs in violation of the FDCA."
Sir, the FDCA is the Federal Drug -- Food, Drug, and Cosmetic Act; is that correct?
MR. ANDERTON: Objection.
THE WITNESS: That's right.
BY MS. SANFORD:
Q And you know that sentence to be true, sir?
MR. ANDERTON: Objection.
You may answer.
THE WITNESS: I am not aware of our other four inspections, so I really can't say.
BY MS. SANFORD:
Q As to the inspection you are aware of, you know that to be true?
MR. ANDERTON: Objection.

You may answer if you know.

THE WITNESS: I am not aware of other four inspections' outcome of FDA.

BY MS. SANFORD:

Q I'm asking you about the one inspection that you are aware of, sir. As to that one inspection, you know this sentence to be true?

MR. ANDERTON: Objection.

THE WITNESS: I would not characterize that. Without knowing the other four inspections' outcome, I cannot answer that question.

BY MS. SANFORD:

Q As to the one inspection, sir, that you are aware of at the Totowa facility, and that was in two thousand -- actually, you're aware of two in 2007 and 2008; correct?

A 2007 and 2008.

Q As to those inspections, sir, is it not true that they revealed numerous and recurring violations of the current good manufacturing practice requirements for drugs in violation of the FDCA?

MR. ANDERTON: Objection; asked and answered.

You may answer.

THE WITNESS: In 2007, FDA's 483, I haven't seen that 483. Also in 2008, I haven't seen the entire 483.

BY MS. SANFORD:

Q So you've never investigated whether that sentence is true as to your portion of the facility, sir?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I haven't seen those 483s, so I really can't make those comments.

BY MS. SANFORD:

Q Have you asked for those 483s?

A No.

Q And by "483," can you tell the jury what you mean, sir?

A 483 involves observation by FDA inspector. At the time she feel it should be done differently.

Q You'll at least agree with me, sir,

so I really cannot comment on this.

BY MS. SANFORD:

Q Certainly you would not want to be in violation of current good manufacturing practices, would you, sir?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Could you rephrase your question again?

BY MS. SANFORD:

Q You wouldn't want to be in violation of current good manufacturing practices, would you, sir?

A That's true.

Q And if we look at Page 6, sir, continuing with Paragraph 11, I'll ask you to read starting with the word "FDA issued." Can you just read that sentence, sir?

Out loud. I'm sorry.

A FDA issues warning letters to Actavis Totowa in 2006 and 2007. Most recently, from March 18 through May 20, 2008, FDA inspected Actavis Totowa's new Riverview Drive facility, and again found numerous and

significant violations of CGMP requirements.

Q Sir, violations of the current good manufacturing practices requirements are not allowed, are they?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I don't know what context they are talking about.

BY MS. SANFORD:

Q In any context, sir.

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: This document doesn't state what violation of GCMP. I really cannot comment on this.

BY MS. SANFORD:

Q My question is just a little outside the document, sir. Just as a general principle, violations of current good manufacturing practices are not allowed?

MR. ANDERTON: Objection; asked and answered.

THE WITNESS: Yeah. We need to follow -- we are to follow CGMP

requirements.

BY MS. SANFORD:

Q Always?

A Always.

Q Okay. And to fail to do that means that the drug would be unsafe?

MR. ANDERTON: Objection; asked and answered.

THE WITNESS: Without knowing the context of that, I cannot comment on that.

BY MS. SANFORD:

Q Do you think that if you have a violation of current good manufacturing practices, that means you're producing a safe drug?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I don't know what you are talking about, violation of CGMP requirement. Unless we know the specific instances, I cannot comment.

BY MS. SANFORD:

Q Do you know the CGMP requirements

there are specific citations observed, failures to meet the current good manufacturing practices?

MR. ANDERTON: Objection.

THE WITNESS: This happened from July 10 to August 2006. I was not there at that time, so I really cannot comment what specific instances they're talking about and what was the company's response. I really cannot answer to your question.

BY MS. SANFORD:

Q My question to you, sir, was that there are cited -- you'll agree that there are cited in this paragraph several instances in which the company is alleged to have failed to meet current good manufacturing practices?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I know the company cited the 483 observation, listed some observation. And based on that 483 observation, company responded to Agency what they felt accurate. I have no

knowledge about those instances, so I really cannot comment.

BY MS. SANFORD:

Q I'm not asking you to comment, sir. I'm asking you whether or not you agree that in this paragraph the Department of Justice -- of the Department of Justice's Complaint they have alleged specific violations of the current good manufacturing practices standards.

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: It reads what it says. But without knowing -- you're asking my opinion, and I cannot answer your question because without knowing all the full context of all the instances, I really cannot comment.

BY MS. SANFORD:

Q So the answer to my question is yes, sir?

MR. ANDERTON: Objection.

THE WITNESS: Can you rephrase your question?

A In September 2007, I was in Little Falls facility.

Q Do you agree that there were significant current good manufacturing practices violations during that time?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: We know we have received at that time few 483 citations, and I have no idea about how company responded to those citations. So without knowing that, I really cannot comment on this.

BY MS. SANFORD:

Q You were the director of quality control at that time, sir?

A That's correct.

Q And you cannot answer whether there were significant CGMP violations in that time period?

MR. ANDERTON: Objection; asked and answered.

THE WITNESS: Without knowing the specific instances that they are

action to protect the public health. During this inspection, FDA observed significant CGMP violations, which were the same or similar to the deviations observed by the FDA -- excuse me -- by FDA during its previous inspections of Actavis Totowa facilities in 2006 and 2007.

And you see, sir, that it goes on to list one, two, three -- five deviations; is that correct?

MR. ANDERTON: Objection; mischaracterizes the document.

You may answer.

BY MS. SANFORD:

Q Well, sir, I will withdraw my question and just look at the sentence.

"These deviations included, but were not limited to, the firm's failure to" -- and you'll see in parentheses, sir, they list five different areas or failures; is that correct?

MR. ANDERTON: Objection.

THE WITNESS: Again, without knowing the specific instances they are referring to, I really cannot answer your question. What context they are talking

about it and what instances they are talking about, referring to, without knowing that, I really cannot answer this.

BY MS. SANFORD:

Q And without looking at those documents, sir, you wouldn't be able to tell whether what you were doing as director of quality control was within current CGMP or not?

MR. ANDERTON: Objection.

THE WITNESS: It could have been there's some 483 observations. And I have no idea what we responded, what documents they have, and what they are referring to in here. Without knowing that, I really cannot comment.

BY MS. SANFORD:

Q And similar to the prior sections that we read, sir, in regard to this specific allegation, you took no steps to find out what those CGMP violations were?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Well, we know that we need to change some of our practices, some of our procedures, the way we handle. Beyond that, without knowing all the specific instances, I really cannot comment to that.

BY MS. SANFORD:

Q And by "we," sir, you mean your department?

A My department means analytical service. That's what you are referring to?

Q Well, at this time, sir, most of the time was spent as director of QA -- QC and analytical services combined. We've already been over that. So I'm using that -- that's what I mean.

A Yeah. Regarding quality control laboratory, without knowing the proper instances, exact instances, I really cannot answer.

Q But you knew you needed to change some of your procedures?

A We always want to improve, improve our operations. That's an ongoing process.

So without knowing the specific instances, I really cannot comment.

Q And if you don't ever go look for the specific instances, you're never going to know them, are you, sir?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Again, FDA in here, they're referring to some specific instances. And I really need to know what's those specific instances so I can accurately respond to your question. Without that, I really cannot answer your question.

BY MS. SANFORD:

Q And that's not something you've done, is it, sir?

MR. ANDERTON: Objection.

You may answer.

BY MS. SANFORD:

Q You haven't gone back to look at what those specific instances are?

A We are every day improving our operations. Every day we are upgrading our

practices. I don't know exactly what they are referring to, what you are referring to.

Q And my point is, sir, in regard to what the FDA or the Department of Justice is referring to, you've never investigated that?

A This is a broader term. We need to -- I need to know the specific instances they are talking about. Like the first instance, they are saying: Have adequate written procedure for quality control unit and to have quality control unit document and investigate the failure of batch of drug to meet specification.

Yes, so we looked into our procedures, and every day we want to improve and make additional improvements. What exactly they are referring to, what instances they are referring to, I really have no idea. But without knowing that, I cannot answer.

MS. SANFORD: I'll object to the nonresponsive part all except for the last two sentences.

MR. ANDERTON: The nonresponsive part to what?

understand it, I'm going to ask that you ask me to rephrase the question. Is that fair?

A That's fine.

Q Okay. And if I ask a question and you answer it, I'm going to assume that you've answered it truthfully. Is that fair?

A That's fair.

Q Okay. Great. Before your role at Actavis as the director of quality control, did I hear correctly that you worked as a lab analyst, not for Actavis, but as a lab analyst?

A In Actavis?

Q No, not at Actavis.

A In my beginning of the career, yes.

Q And as a lab analyst -- is that the right term to use? You were --

A Chemist.

Q A chemist. Okay.

Is "chemist" the term that you use to refer to your lab analysts at Actavis?

A Yes.

Q When you were in the role of chemist, and I realize for some other

Q So you agree with me that in that little over one-year time frame that you were there, it went from a hundred products down to roughly one product? You agree with that?
A That's correct.
Q As the director of analytical services, tell me in your words why roughly 99 products were discontinued.
MR. ANDERTON: Objection.
I instruct the witness to answer only with respect to Digitek.
THE WITNESS: I have no idea.
BY MR. MILLER:
Q You have no idea. Have you ever asked anybody?
A No.
Q Were you ever curious?
MR. ANDERTON: Objection.
You may answer.
THE WITNESS: Company made the decision.
BY MR. MILLER:
Q Does it have anything to do with safety?

A Repeat that again, please.

Q Certainly. Well, we're inside this big lab and you're testing anything from pills to the actual blended powder; right?

A (Witness shakes head.)

Q It has to somehow get inside the lab for your chemists to test it; correct?

A That's correct.

Q How did it make its entry? How did it get to your chemists?

A The QA takes the samples from manufacturing. They bring the samples in the laboratory, gets logged in in the logbook. Then samples are temporarily stored in a cabinet. Then depending on the requirement, the supervisor assigns the particular samples to different chemists. And eventually it gets tested, reviewed, and then released to QA.

Q Well, when a sample is ultimately given to the chemist to test, were there any fences or were there any like this drug comes in and needs to go to a certain group of chemists or were all your chemists qualified to test whatever sample came through the door?

MR. ANDERTON: Are you saying "fences"?
MR. MILLER: Yes.
MR. ANDERTON: Okay.
MR. MILLER: It might be the wrong term.
MR. ANDERTON: I just wanted to make sure I knew what word you were saying.
BY MR. MILLER:
Q Okay. If you don't understand what I'm saying, I'll --
A I don't understand "fences."
Q I've been in places before where when you say somebody can't do something, he's got a fence around him. So I don't know what term they would use. Perhaps you didn't use such a term.
Could all -- did you have a group of chemists that were qualified to do content uniformity testing, or were all chemists capable of doing all tests? How did you divide it up?
MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Well, some people are more experienced on handling raw material testing, which are basically weight chemistry analysis. Some people are more experienced on instrumental analysis, like HPLCs. So accordingly, the work was assigned.

BY MR. MILLER:

Q Okay. Let's just say something came in for HPLC testing. That's high performance liquid chromatography?

A Chromatography.

Q If it was a particular type of drug, would you say, "Oh, no. That product needs to go to this person"? Or once something came in for HPLC, all HPLC analysts were capable of testing that product?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Basically any HPLC chemist can handle all the product, but certain products are very technique-dependent.

BY MR. MILLER:

Q Very technique?

A Technique. It may require liquid extraction. Those are very technique-dependent.

Q If a technique-dependent product came in, did you have a specific tester or group of testers that you liked to use?

A They are more experienced on that product.

Q More experienced on that product? What were some of the products that were more technique-dependent?

MR. ANDERTON: Objection. I instruct the witness not to answer or to answer only with respect to Digitek.

BY MR. MILLER:

Q Was Digitek a technique-dependent product?

A No.

Q So if Digitek came in, it could go to any of the HPLC testers?

A That's correct.

Q And if there was a content

we respond to FDA, then quality assurance determine what it is that we need to improve and communicate it to every department.

Q Do you have any specific memory of an FDA 483 inspection going through that process and then becoming a project that you worked on? Did you ever work to specifically improve an observation found by the FDA 483 in either 2006, '7, or '8?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Yes. We had a series of quality system improvement plan; and it may happen there, that what it is that we need to look into.

BY MR. MILLER:

Q Were you a member of the quality --

A System improvement plan, QSIP.

Q QSIP. Were you a member of QSIP?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Yes, I was participating in QSIP plan.

BY MR. MILLER:

Q And how often did -- who else was a member of the QSIP plan?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: QA, manufacturing, R&D, quality control, IT.

BY MR. MILLER:

Q How often -- were there meetings held by the QSIP?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Yes.

BY MR. MILLER:

Q Am I accurate in calling it the QSIP? Was that a group? It's a plan but what --

A It's a plan.

Q What did the group call themselves, or did you have a name?

A There is no group name. That's it.

Q If you were going to meet, how did you identify everybody?

A QSIP.

Q Okay. QSIP. All right. How often did QSIP meet?
A I believe it was almost every week.
Q Was there a report that was done from the weekly get-together of QSIP?
A QA may have produced. I have no -- I don't remember.
Q I would like to hand you what was previously marked as Exhibit 68. Sir, I'll represent to you that this is the findings of an FDA inspection at Actavis Totowa in July-August of 2006. And it's your testimony that you've never seen this document before; is that correct?
A That's correct.
Q But before working at Actavis, you have, in fact, seen a document in this form, an FDA 483?
MR. ANDERTON: Objection.
You may answer.
THE WITNESS: Yes.
BY MR. MILLER:
Q You're familiar with the format of it?

A Yes.

Q And it goes on to give amplifying information. Actually, before I get into that, you would agree with me that this is the quality control unit, a subset of which is the quality control, the chemists. They fall under this, what we have discussed as the quality control unit; correct?

A Quality control laboratory is part of the quality control unit.

Q And you agree with me that all products, hundred products are evaluated and tested with that quality control unit; is that correct?

A Quality makes the decision. Quality control laboratory tests the product. Quality assurance decides reject or acceptance of that product.

Q Of the hundred products that were being made when you were hired in April of 2007, were all of them being tested by the Actavis quality control unit or were some of them being sent somewhere else to be tested?

A Some product needed -- we don't have

Q And Digitek is tested by that lab that reports to that quality control in the group quality control unit; is that fair?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Quality unit decides the acceptance or rejections of the product to be in the market. Quality control tests the product. Manufacturing manufactures the product. Packaging package the product. The overall quality unit decides whether to release or reject the product.

Quality control is one of the unit to test the product. So quality decides not just only quality control lab; the entire quality of the product.

BY MR. MILLER:

Q Fair enough. And one of those products is Digitek?

A Digitek.

Q Thank you. Then they go into specifics, and it says: "Specifically, there is no assurance that the Quality Unit can be

relied upon to fulfill its responsibilities to assure that all drug products released to the marketplace meet the requirements for identity, strength, quality, and purity that they purport to have."

Did I read that correctly, sir?

A Yeah, you are reading what it says.

Q Okay. And then as quality control director in the latter part of April 2007, were you made aware of this finding through any other means besides this 483?

MR. ANDERTON: Objection; mischaracterizes his testimony.

You may answer.

THE WITNESS: First of all, this particular 483 was issued prior to my employment in Actavis. And I was not given this 483, and I was not aware what specific circumstances they are referring to to come to that conclusion, to come to that interpretation.

BY MR. MILLER:

Q And you also are not aware of the response that the company made?

BY MR. MILLER:

Q Certainly. What does "all products" mean, just the two words together, "all products"? You're director of quality control at Actavis and someone says to you "all products"; what does that mean to you?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: That means all products.

BY MR. MILLER:

Q And at Actavis, would that be roughly a hundred products that we discussed?

A That's all hundred products.

Q Is Digitek one of those hundred products?

A Digitek is one of the products.

Q It goes on to say: "Batches of drug products that initially failed to meet release specifications were released into interstate commerce without being fully investigated, all laboratory data was not included with the batch records and manufacturing deviations were not always documented."

Sir, you agree with me that that is a violation of CGMP?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: This is observation of the investigator. Without knowing all the facts, without knowing the specific instances, I really cannot answer to this question.

BY MR. MILLER:

Q And without knowing --

A This is generalization of their interpretation.

Q Okay. So without knowing any more facts, you wouldn't be able to act upon that?

A Well, I would ask that what documents that we provided to them, to clarify those, their interpretation, what response we have given to them, what they are referring to for this, to come to this particular conclusion.

Q Okay. Of the quality control unit subareas, which we identified as quality assurance, quality systems, training, quality

unit, we've established that, one, it pertains to the quality assurance. Does it pertain to quality systems?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Well, at that time I don't know -- I don't know that Actavis' organizational structure, whether quality system was a separate entity in the quality unit. I have no idea, so I really cannot answer that.

BY MR. MILLER:

Q Okay. Quality system isn't your bailiwick. Fine. Does it apply to quality control?

A Quality control is a part of quality unit.

Q But does this specific observation, Observation 1, which points out that the quality control unit lacks authority to fully investigate errors that have occurred, does this observation pertain to quality control at Actavis?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Yes. It says laboratory data was not included.

BY MR. MILLER:

Q Fair enough. Now that we have read Observation 1 and you have identified that it pertains to the quality control department at Actavis, which you took over in April of 2007, was this information relayed to you in any way in order to make improvements?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Yes. QSIP plan.

BY MR. MILLER:

Q So there was a QSIP plan that reflected this finding, and it was an issue that you felt you needed to improve?

MR. ANDERTON: Again, mischaracterizes his testimony.

THE WITNESS: QSIP plan has all the different areas, the training, documentation, updating all the procedures. All are included in the QSIP plan.

BY MR. MILLER:

Q Let's take a look at Observation No. 2. Observation No. 2 addresses laboratory records. As a director of quality control, do laboratory records fall under your division?

A Yes.

Q Did you keep laboratory records for all drugs?

A Yeah.

Q Did you keep laboratory records for Digitek?

A Yes.

Q If there's an observation or an issue that affects laboratory records across the board, would you agree with me that it also affects Digitek?

MR. ANDERTON: Objection; mischaracterizes the document.

MR. MILLER: I didn't bring the document up.

BY MR. MILLER:

Q But go ahead. You may answer.

A Repeat that question again.

Q Certainly. Laboratory records that

MR. MILLER: Certainly.

BY MR. MILLER:

Q Were you familiar with the fact that Observation 2 of the FDA 483 dated July 2006 identified that laboratory records are deficient in that they do not include a complete record of all data obtained during testing?

A I don't know. Maybe the records were misplaced or -- without knowing the facts, I really cannot answer.

Q I'm asking if you were aware this was a problem. Was this something that needed to be fixed?

A As I said, I never received or reviewed this 483. All we know is through QSIP program, so we need to improve certain areas.

Q Were you ever told about this information in any other format?

A No.

Q No?

A Except in QSIP.

Q In QSIP? Did QSIP ever say to you:

Director of quality control, this is Observation 2 from the 2006 FDA 483; we want you to fix it?

A QSIP says what areas need to be improved, and there was a plan to improve those areas and those practices.

Q Were you ever tasked to specifically improve this finding, Observation 2?

A Yes. We upgraded our documentation system, the chemists to document their findings in the notebook, and that all part of the QSIP program.

Q So you were aware of this, and you did work to make this problem better?

MR. ANDERTON: Objection; mischaracterizes his testimony.

You may answer.

BY MR. MILLER:

Q Is that true?

A Through QSIP plan.

Q You did that through the QSIP plan?

A Right. Company had a QSIP plan.

Q In fact, you were told: This is Observation No. 2 of the FDA 483; we want you

mischaracterizes the document.

You may answer.

THE WITNESS: Repeat that question again.

MR. MILLER: Certainly.

BY MR. MILLER:

Q Will you agree that the first row after the title August 2006 GMP Inspection Totowa is titled 483 Observation 1?

A Yes.

Q Does the W/L 1 mean anything to you?

A I can interpret as Warning Letter, Item 1.

Q Okay. And Observation 1, the next line with the column that's identified as Observations, and looking at 483 Observation 1 says: "Failure of the Quality Unit to fulfill its responsibilities." Specifically: "Failure to fully investigate errors; all lab data not included with batch records; manufacturing deviations not always documented."

Do you have an understanding that that reflects the findings of the Exhibit 68,

which was Observation 1 of the 483?

MR. ANDERTON: Objection.

BY MR. MILLER:

Q You're more than welcome to take the time and compare the two if you like.

MR. ANDERTON: You may answer.

THE WITNESS: Yeah. It's pretty much taken out from this Observation 1.

BY MR. MILLER:

Q Okay. So looking at Observation No. 1 on a document that was provided to us by Actavis, you agree that it identifies Totowa action items and documentation needed. The responsible person for this Observation 1 is Scott Talbot. And you identified him earlier as your direct supervisor?

A Right.

Q And what was his title?

A Site head of quality.

Q Site head of quality. Okay.

And then Dan Bitler, what was his title?

A Was the director of quality

A I never saw this document before.
Q Okay. Then Observation No. 2 of the 483 as it's rewritten on this Actavis company document states: "Quality Unit failed to assure that lab notebooks include all data generated during testing."
Did I read that correctly?
A Yes.
Q And you agree with me that it equates to the observation that we went over in Observation 2 of the actual 483?
A Yeah, it came out from Observation No. 2.
Q And if we look over here to the responsible person and comments, it simply says "Roy." Do you have any reason to doubt that that is not you?
MR. ANDERTON: Objection.
THE WITNESS: That's me, Roy.
BY MR. MILLER:
Q That is you?
A Right.
Q Were you aware that you were the responsible person for the Observation No. 2,

specifically, "Quality Unit failed to assure that lab notebooks include all data generated during testing"?

MR. ANDERTON: Objection; asked and answered.

THE WITNESS: I was not in Actavis at that time when that happened from -- this is from 2006.

BY MR. MILLER:

Q Did they know that you were coming to work for Actavis during the inspection of 2006?

A I don't think so.

Q I wouldn't think so. Okay. Then explain to me why a company document would have "Roy" written on it. You agree that it pertains to you?

A I don't understand your question.

Q Well, I'm trying to understand this document. You agree with me that it pertains to the FDA 483 Observation 2. We agree it's similar findings and that the responsible person is identified as you. Do you recall being identified as the responsible person for

Q And did you or anyone that reported to you work on that action item?

A Yes. We had a program based on QSIP. All the chemists were retraining. So this document was updated probably based on those training documents.

Q Okay. And when the analysts were retrained, they were retrained about lab notebooks across the board, not any particular product; correct?

A Across the board.

Q Across the board?

A Documentation practices.

Q The problem you agree was identified across the board, so the training was across the board?

MR. ANDERTON: Objection.

BY MR. MILLER:

Q You can answer.

MR. ANDERTON: Wait. Mischaracterizes his testimony.

You may answer.

THE WITNESS: The training was given specifically in here what it

mentioned, the documentation practices. They were specifically instructed to document every observations and all the procedures they are following.

BY MR. MILLER:

Q For all products?

A All products, for any products.

Q Any product.

And "Procedures are in place where all data generated during testing are entered into the new lab notebooks."

Did I read that correctly?

A That's correct.

Q Do you understand what the action item meant when it says "new lab notebooks"? Were the lab notebooks changed or altered?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Yes. We make it more simpler, the new notebooks. Before it was like 200 pages of bound book. And we have different type of notebook, ready lab notebook which is prenumbered.

BY MR. MILLER:

Q And those lab notebooks, either the old style or the new styles referred to in this action item, either variant had an index in the front of it; isn't that correct?

A That's correct.

Q Fair enough. I want to go back and take a look at Exhibit 68, which, again, is the 483. And this time I want to take a quick look at Observation No. 2. It says specifically -- one second. I want to zoom in a little bit more.

"Specifically, the Quality Unit failed to assure that laboratory notebooks include all data generated during testing and that analysts document in their laboratory notebook all sample preparation and testing at the time it occurs. Additionally, SOP QC-59, Investigation of out of specification test results (OOS) is not always followed." And then it says, "For example."

As someone who's been in the quality control industry for pharmaceutical labs for quite some time and someone who has read 483s

in the past, is it a fair statement to say that "for example" means to me that these are some examples but yet there are other examples out there; it's not an exclusive list?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Not necessarily. Maybe this is only example.

BY MR. MILLER:

Q Right. But what does "only example" mean to you?

A Maybe only one incidence.

Q So you think --

A That all depends on FDA investigator's interpretation at that time.

Q But you would interpret "for example" as either being only a couple examples or an exhaustive list?

A Repeat that again.

Q Yeah. You would interpret it, as a director of quality control, as potentially either being only a couple exhaustive examples or would you consider it to be a few of many examples?

MR. ANDERTON: Objection.
You may answer.
THE WITNESS: We look into every observations very carefully and make necessary improvement depending on that observation.
BY MR. MILLER:
Q I'd like to take a look at the next page, if you would, sir, Observation No. 3. And Observation No. 3 says: "The responsibilities and procedures applicable to the quality control unit are not fully followed.
"Specifically, there is no assurance that the Quality Unit can detect discrepancies in reports for which they are responsible. Data and reports reviewed and approved by the Quality Unit were not accurate and complete and did not adhere to established procedures. In addition, changes are not always documented in the change control system."
Were you made aware of this observation through any means, sir?
A May have been through quality system

improvement plan.

Q And as the director of quality control, did you determine this to be a problem across the board for all products?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: As a director of quality control, we like to improve our operation all the time. As I said before, it was a -- pharmaceutical industry is a continuously changing environment. New regulation comes up, new industry practices, and we need to improve. Based on FDA observation, based on discussion in the trade meeting, we always improve. This could be result of that.

BY MR. MILLER:

Q And by way of example, this observation, Observation No. 3, you want to improve this for the entire lab. You didn't go to the examples that they gave and just fix the examples; you fixed it throughout the entire lab; is that correct?

MR. ANDERTON: Objection.
THE WITNESS: That's correct.
BY MR. MILLER:
Q I'm sorry?
A That's correct.
Q That's correct. And you would agree under the quality unit, that this is a quality control issue; may involve other departments, but it is a quality control issue?
A It says the quality issues, not quality control laboratory issues specifically.
Q Do you recall working on this observation or any form of this observation through the QSIP team?
MR. ANDERTON: Objection.
You may answer.
THE WITNESS: I need to go to the specific citation before I can respond to you.
BY MR. MILLER:
Q Well, if we take a look at Exhibit 84, specifically the third page, Actavis 00508283, where this document outlines

Q And that training pertained to all drugs, all products?
A All documentation.
Q All documentation of all products?
A All products.
Q Let's take a look at Exhibit 68 again, the FDA 483. And this time we're going to go to Observation No. 4. Observation 4: "Written records are not always made of investigations into the failure of a batch or any of its components to meet specifications.
"Specifically, investigations were not conducted when out of specification results were generated. Samples were retested and the original results were not invalidated."
Did I read that correctly?
A Yes.
Q Is it important for a chemist working at a pharmaceutical lab to investigate out-of-specification results?
MR. ANDERTON: Objection.
You may answer.
THE WITNESS: In laboratory,

anytime we observe any out of specification, yes, we investigate.

BY MR. MILLER:

Q And was this one of the items observed by the FDA that you would have rectified through QSIP?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I clearly need to look into the specific instances where that happened. So without that, I really cannot answer.

BY MR. MILLER:

Q Well, if we take a look at Exhibit 84 that was identifying which observations were assigned to who, you agree with me on Actavis 508 ending in 283 that the 483 Observation 4, investigations were not conducted into lab OOSs, or out of specification, that this action item went to Scott Talbot and Roy?

A That's right.

Q And Roy is you; correct?

A That's correct.

Q And seeing this document, does that refresh your recollection on working on this action item?

A Yes. We improved our OS investigation procedures; that is, DOI QC-59. And we improved to adequately investigate the laboratory investigation.

Q And you would agree with me that if a lab chemist is not properly investigating an OOS, then that is an issue or problem with the lab, not that one incident where it occurred; is that correct?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: This is interpretation of FDA investigator at that time. Ideally I need to go back and check what it says in QC-059 12 at that time and what was the practice at that time was followed.

If the chemists were following that particular practices and procedures, they are following the procedures. It may not be liking of FDA investigator, so

that's what their comments were that was not, in their mind, it was not properly conducted.

BY MR. MILLER:

Q Do you recall working on the action items to rectify this situation?

A Yes. We updated our investigation procedure.

Q And you updated investigation procedures for all products?

A That's the lab procedure. That involves all the products.

Q If we take a look at Observation 5 on the 483, it states that: "Input to and output from the computer are not checked for accuracy.

"Specifically, audits were not conducted of the TotalChrom Data Acquisition System used to run the HPLC instruments during analysis of drug products. Sample injections, processing methods, and sample weights were not reviewed or verified for the accuracy of reported sample results during testing of in-process, finished product and stability

samples."

Did I read that correctly?

A Yes.

Q As the director of quality control of Actavis, do you take that to apply to all products?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Whenever we improve our practices and procedures in the laboratory, that's the practice and procedures encompasses all the products.

BY MR. MILLER:

Q Do you recall being assigned this as an action item for you to work on through QSIP?

A May have been.

Q And, in fact, if we look back at Exhibit 84, you will see that Observation 5: Audits were not conducted of the TotalChrom Data Acquisition System used to run the HPLC instruments. And the action item goes to in the last column Scott Talbot, Roy, and Nilesh?

Do you recall now working on this

action item?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: These are action item may have been completed before my time, before I joined Actavis.

BY MR. MILLER:

Q Well, that date in the second-to-last column says July 12 of 2007. If we go back to the first page, we'll see that that says "Date verified correction." Do you see that, sir? And you would agree with me that you were on the premises July 12 of 2007?

A That's correct.

Q Do you recall working on this action item?

A Yeah. Maybe the last item was pending and -- during that time I was there.

Q As the director of quality control for Actavis labs and the chemists, would you agree that failure to conduct audits of the TotalChrom data acquisition system used to run HPLC is a violation of the CGMPs?

483?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Could you be more specific?

MR. MILLER: Yes.

BY MR. MILLER:

Q Were you involved in rectifying the problem as outlined in Observation 6?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: No. During that time, I didn't work on any cleaning validation methods.

BY MR. MILLER:

Q But if we go back to Exhibit 84, and that was Observation 6, in fact, from this document, it appears that the column which identifies who is responsible for the action items is blank. You would agree with that?

A Yes.

Q And if I go through Observation 7, I don't see your name, so we'll speed this up a little bit. Observation 8, not identifying

were not identified with product name and batch number; correct?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Chemists may have a different way of identifying those solutions, and FDA's interpretation is to be identified by product name and batch number. They may have a different practices.

BY MR. MILLER:

Q In your role as responsible person for the items that we've addressed, do you recall filling out any report or information regarding what actions you took?

A We discussed in our QSIP meeting and produced the procedures that we have updated, produced the document that the chemists were trained with those procedure, and that's what recorded.

Q After all of these observations were identified regarding the lab at Actavis, did you feel that your chemists were competent and capable to perform the functions required of

A I was not aware of that particular document.
Q You were not what?
A I was not aware of that document.
Q You were not the what of the document?
A I was not knowledgeable about that document.
Q You were not knowledgeable about that document.
So if the company sends a letter to the FDA, as the director of quality control, you're not going to give a document any weight unless you are allowed to look at it?
A I was not knowledgeable of that particular document.
Q Okay. If we go back --
A I was not given that document.
Q If we go back to Exhibit 69, which is the Actavis Totowa monthly update in which we read into the transcript: We appreciate the FDA's detailed inspection and thorough observations. We agree that the observations cited on Form 483, Items 1 through 15, are

correct and constructive and have identified the need for improvements in our operational procedures and practices at the Actavis Totowa Little Falls, New Jersey, facility.

And is it your testimony here today, sir, that if the company, specifically Nasrat Hakim, sends such a letter to the FDA, that you don't believe it carries any weight in your responsibilities at the company unless you are given a copy of it?

A No. It says that we need to improve our operational procedures. That doesn't mean that we are in violation. And it clearly says need for improvement in our operations.

Q Did the FDA 483 investigations have anything to do with the 100 products we discussed the production line being stopped?

MR. ANDERTON: Objection. I instruct the witness to answer only with respect to Digitek.

THE WITNESS: Repeat that again.

MR. MILLER: Certainly. Well, in light of that objection, I'll

BY MR. MILLER:

Q How does eventually recalling a number of products relate to the fact that Actavis explained that this is part of a larger recall of products stemming from an on-site FDA inspection?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I have no idea.

BY MR. MILLER:

Q But you agree that Actavis did, in fact, recall a larger group of products? You agree with that?

A Yes, Actavis recalled a number of products.

Q Do you agree that the larger recall of products stemmed from an on-site FDA inspection?

MR. ANDERTON: Objection. I instruct the witness not to answer except with respect to Digitek.

Do you understand my instruction?

THE WITNESS: Yes.

Could you repeat your question again.

MR. MILLER: Yes.

BY MR. MILLER:

Q Was the recall of Digitek part of a larger recall of products stemming from an on-site FDA inspection?

MR. ANDERTON: And I, again, object and instruct the witness to answer only with respect to Digitek.

MR. MILLER: My question was only with respect to Digitek.

MR. ANDERTON: Not really.

BY MR. MILLER:

Q Sir, the question is: Was Digitek part of a larger recall of products stemming from an on-site FDA inspection?

MR. ANDERTON: Again, I object and instruct you to answer only with respect to Digitek.

BY MR. MILLER:

Q And with that instruction, you're okay to answer.

MR. ANDERTON: You may answer

with that instruction.

THE WITNESS: I really cannot answer this question because I don't know what triggered to recall the products. I was not part of the discussion. I was not part of that meeting.

MR. MILLER: Fair enough.

BY MS. SANFORD:

Q Sir, I'm going to hand you what was previously marked as Exhibit 25.

MR. ANDERTON: 25?

MR. MILLER: 25.

BY MR. MILLER:

Q Sir, have you seen this document before?

A No.

Q Have you ever -- okay.

Now, this document, I'll represent to you, provided to us by Actavis, specifically Document 0028242 titled a "Revised Warning Letter" from the FDA dated February 1 of 2007. Are you familiar with the term the "Revised Warning Letter"?

A No.

significant deviations from the current good manufacturing practice regulations set forth in Title 21, Code of Federal Regulations, Parts 210 and 211, in conjunction with your firm's manufacture of prescription drug products.

Are you familiar that a letter February of 2007 went to the Little Falls plant regarding an inspection that was conducted in July and August of 2006?

MR. ANDERTON: Objection; asked and answered.

BY MR. MILLER:

Q It's okay to answer.

A No, I was not familiar with this letter.

Q Okay. It goes on to discuss findings. And this paragraph where I just read where it talks about documented significant deviations from the current good manufacturing practice, now, would that apply to the quality control department that you're in charge of in April of 2007?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Without going through all the details, I cannot respond to your question because it's significant observations or deviations pertaining to where? We need to go through all these observations.

BY MR. MILLER:

Q Let's do it.

A Yeah.

Q It says: The inspection revealed that drug products manufactured in your facility are adulterated within the meaning of 21 USC 351(a)(2)(B), Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, referred to as the Act.

As a director of quality control at Actavis, what does a term "adulterated" mean when it's used on a pharmaceutical product?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: Quality control laboratory tests the product as per the procedure and forward the results to

quality assurance to act on it. That's what the function of quality control unit.

BY MR. MILLER:

Q Okay. I didn't ask about the function of the quality control unit. My question is specifically the term "adulterated." If the FDA uses the term "adulterated," what does that term mean as it's used in conjunction with a pharmaceutical product?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: It's a broad terminology of adulteration in here.

BY MR. MILLER:

Q I'm sorry?

A It's a broad terminology of adulteration in here. This is a type of word that FDA, they use in their document, either in 483 or in warning letter. We need to go through each specific observation. Then we can respond to specific question.

to see in the letter?

MR. ANDERTON: Objection.

THE WITNESS: Could you be more specific? Additional findings, what are you referring to?

BY MR. MILLER:

Q If a warning letter says "the significant observations included but were not limited to the following," does that mean that the significant observations we're going to read about is not a complete list, that there are observations beyond what are on the document?

A That is their standard terminology they use. Whatever observations they felt they observed, they list all those observation. They have shown there may be other observations, may not be. So I really cannot comment on this particular statement.

Q Fair enough. Well, specifically No. 1 states: "Significant deficiencies were found in the operation of your firm's quality control unit, and as a result there is no assurance that many drug products manufactured

and released into interstate commerce by your firm have the identity, strength, quality, and purity that they purport to possess."

If that information was provided to the company seven or eight weeks before you took the position of director of quality control, do you feel that it's important that you know that?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: As I said, we are working through our QSIP plan. Those -- any observations are included in QSIP plan and we are improving our practices and procedures.

BY MR. MILLER:

Q Did the QC plan ever discuss specific findings from the warning letter?

MR. ANDERTON: Objection; mischaracterizes his testimony.

BY MR. MILLER:

Q It's okay to answer.

MR. ANDERTON: You may answer if you know.

THE WITNESS: I don't know.
BY MR. MILLER:
Q Let's go to Page 4.
MR. ANDERTON: Of the warning letter?
MR. MILLER: Yes.
BY MR. MILLER:
Q And it's Observation No. 7. It says: "Your firm's cleaning validation studies were found to be inadequate and, as a result, there was no assurance that equipment is adequately cleaned between the manufacture of different drug products."
Were you aware, as the quality control -- as the director of quality control, that there was an issue with cleaning validation studies seven weeks prior to your taking that position?
MR. ANDERTON: Objection.
You may answer.
THE WITNESS: Was I aware of this cleaning validation?
BY MR. MILLER:
Q Yes.

A No.
Q Did you ever become aware that there were issues with cleaning validation studies?
MR. ANDERTON: Objection.
You may answer.
THE WITNESS: We may have a QSIP item to improve.
BY MR. MILLER:
Q And it says "For example," and it specifically identifies: "Cleaning validation was performed for the process trains without evaluating for sample recovery for numerous products, including" -- there's a redaction, and it follows up with "Digoxin Tablets, USP, .25."
Were you aware -- actually, do me a favor and explain to me, as the director of quality control, do you have an understanding what cleaning validation performed for the process train indicates?
A Cleaning validations are two part. One is the actual cleaning procedures, how the equipments are going to be cleaned; and the second part is to take the test samples and

test in the laboratory. And the methods that you're going to use, that method needs to be validated. So there are three parts in there.

Q Is performing a cleaning validation for a process train without evaluating for sample recovery, is that a violation of CGMP?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I wouldn't consider as a violation of CGMP. Maybe document needs to be upgraded, needs to be improved.

BY MR. MILLER:

Q If we go back to the first page, we discussed that in that first paragraph it says they identified significant deviations from the current good manufacturing practice. And would you agree that they're going on to list significant deviations from the current good manufacturing practice?

MR. ANDERTON: Objection; mischaracterizes the document.

You may answer.

THE WITNESS: Again, you are

repeating the same thing over and over again. This is FDA's interpretation, FDA's observation and findings. I really cannot comment on that. And these all happened prior to my employment at Actavis.

BY MR. MILLER:

Q You agree that if FDA were to identify significant deviations from current good manufacturing practice, that it would be important for the lab to improve on those identified deviations?

MR. ANDERTON: Objection. You may answer.

THE WITNESS: Yes, sometimes, yes. We're going to improve our operations. We always want to improve our operations.

BY MR. MILLER:

Q If an observation is identified by the FDA and you don't improve, could the outcome be that the production line is going to be shut down?

MR. ANDERTON: Objection.

BY MR. MILLER:
Q It's okay to answer.
MR. ANDERTON: You may answer.
THE WITNESS: Not necessarily.
BY MR. MILLER:
Q You indicated that you didn't read the 483 from 2008. Did you ever request a copy of it?
MR. ANDERTON: Objection; asked and answered.
BY MR. MILLER:
Q Okay to answer.
A No.
Q No. Do you recall being given a copy of it?
A No.
MR. MILLER: I would like to mark Exhibit 86.
(Plaintiff's Exhibit No. 86 was marked for identification.)
BY MR. MILLER:
Q Sir, I'll represent to you this is an e-mail that was produced to us from Actavis, specifically Actavis Document 506518.

A Naturally, one observation is better than hundred.

Q Naturally, okay. You understood that time. Thank you.

How long did you stay in the lab with Phyllis Lambridis, the FDA inspector, and your two managers?

A With FDA inspector?

Q Yes, sir.

A Maybe one whole afternoon.

Q I would like to discuss the findings of that FDA 483.

It says: "The responsibilities" --

MR. ANDERTON: What page are we on?

MR. MILLER: We are on Actavis 028225, which was previously marked as Exhibit 26.

MR. ANDERTON: Okay. First page of the document?

MR. MILLER: Yes.

MR. ANDERTON: Thank you.

BY MR. MILLER:

Q And Observation 1, and above that it

says: "Quality System": "The responsibilities and procedures applicable to the quality control unit are not fully followed."

As the director of quality control of Actavis in March of 2008, is it important that the responsibilities and procedures applicable to the quality control unit are followed?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I think you are generalizing all these observation. I was the head of quality control laboratory. Here they are referring to quality control unit means total quality system -- quality unit. Nowhere it says that quality control laboratory has the problem or has the issues.

BY MR. MILLER:

Q All right, sir. Then it goes on to say: "Specifically, the Quality Unit routinely failed to document, investigate and address product quality issues at the time of

occurrence including in-process, finished product and stability out of specification analytical results."

Did I read that correctly, sir?

A Yes.

Q And would you agree with me that finished product, stability out of specification analytical results are part of quality control?

A I think you are taking out of context from here, from this statement.

Q What am I taking out of context?

A Quality control laboratory tests the product --

Q Yes.

A -- produce, give the documents to quality assurance. There are other quality control organization. They determine -- and they review those documents and determine the product disposition. Nowhere it says that quality control laboratory didn't test the in-process, finished product, and stability testing.

Q I totally agree it's not saying it

wasn't tested. It says: "The Quality Unit routinely failed to document, investigate and address product quality issues at the time of occurrence including in-process, finished product and stability out of specification analytical results."

A You are asking me to respond to somebody else's function, which I am not aware of. Quality control unit encompasses quality system, quality assurance, quality control laboratory, QAIG, training document. You need to be very more specific in that regard.

Q Let's look at Observation 4, sir. And it's going to be on page lower right 28230. Observation 4 specifically says: "Determinations of conformance to appropriate written specifications for acceptance are deficient for in-process materials."

Is that a function of the quality control department?

A That is a function of quality department.

Q Is that a function of your department in quality control?

A I am the quality control laboratory head.

Q Is that a function of the quality control laboratory?

A We review -- we test and we submit our results to quality assurance. They decide whether to accept or reject the batch. Acceptance and rejection is not under my control.

Q Is this --

A Was never under my control.

Q I'm sorry. Excuse me.

It says Specifically, and it goes on to say: Although three out of specification results were obtained for blend uniformity at the Right-Top sample location for Digoxin Tablets .125 milligram -- and it goes on to give the lot numbers and the dates -- no manufacturing investigations were conducted. Additional samples were used to retest the blend and were reported. Lot 70207A1 was released on June 7, '07, and Lot 70770A1 was released on November 30, '07, by Quality Unit. Lot 7014A was not released due to atypical

BY MR. MILLER:

Q Who was in charge of quality assurance prior to Dan Bitler?

A I don't know.

Q Let's take a look at Observation 5. And specifically Observation 5 says: "Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that components, in-process materials, and drug products conform to appropriate standards of identity, strength, quality and purity."

Did I read that correctly?

A Yes.

Q And does that fall squarely under quality control?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: The laboratory test procedures were developed at the time of product approval with FDA. That particular methods, specifications were developed by R&D, analytical R&D and

product development. And based on those submissions, we obtain our approval. And laboratory, we follow those test procedures to test the product.

BY MR. MILLER:

Q My question is: Does Observation 5 pertain to quality control in the lab?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I said laboratory tests the product based on the approved procedures from FDA, test procedure.

BY MR. MILLER:

Q If procedures were being done as they were approved by the FDA, can you explain why there's an observation suggesting the opposite?

A I have -- that's what I state in the beginning. This is interpretation of FDA's inspector. Those procedures and specifications were approved by FDA through our ANDA.

Q As you were in the lab and the inspector was inspecting the lab and you were

A I don't remember the exact date.
Q Give us a time frame, sir.
A Maybe from May.
Q May of 2008?
A May of 2007.
Q Was QSIP -- is there a QSIP that's specific to Digitek?
A QSIP is specific to the entire quality system to improve.
Q So the QSIP applies to all products?
A QSIP applies to our practices and procedure of entire Actavis Totowa, LLC.
Q Is there a QSIP that is specific to Digitek?
A I cannot respond. I don't know about that.
Q If there is one, you don't know about it?
A I don't remember.
Q Would you know about it if there was one? Is there a place --
A It should be in the QSIP plan.
Q And do you keep a copy of the QSIP plan in your files, sir?

Those are two different answers, and so I need to figure out which one applies here.

A We are not producing any digoxin, so I don't think there is any digoxin QSIP plan.

Q To your recollection, as you sit here today, there's nothing that specifically addresses digoxin after the recall?

A That's correct.

Q And digoxin is not being produced -- has not been produced at your facility since the recall; is that correct?

A That's correct.

Q Sir, there is something also called a corrective action plan or corrective action preventive action plan?

A Right, CAPA.

Q When was that put in place?

A That was started sometime in -- that's sometime in 2007.

Q Are you a member of the CAPA team?

A CAPA relates to everybody, all the department.

Q In your position as director of analytical services, are you involved in

writing or --

A Yes. If that particular assignment, that particular CAPA comes assigned to my department, yes, I will be involved.

Q Is there a CAPA for each department?

A CAPA relates to specific incidents and what corrective actions that we are going to take for that particular incidence.

Q And is that a result of FDA inspections as well, sir?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: No. That particular CAPA program was always there in 2007.

BY MS. SANFORD:

Q Did it have anything specific to Digitek or digoxin in the CAPA plan?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: We are not manufacturing any digoxin right now.

BY MS. SANFORD:

Q It was in place in 2007 is your

testimony?

A Right.

Q You were manufacturing digoxin at that time?

A Right.

Q Did the CAPA plan specifically apply to digoxin?

A I was -- there was no CAPA was assigned to my department during that time, so I was not aware of it. CAPA is called for by QA, quality assurance.

Q So you were responsible for putting CAPA together in 2007?

MR. ANDERTON: Objection.

THE WITNESS: Again, you are misrepresenting the facts.

BY MS. SANFORD:

Q I don't mean to misrepresent anything. I'm trying to understand.

A CAPA is controlled and coordinated by quality assurance department. They maintain the CAPA. If the particular incidence relates to my action that I have to attend to that, then that could be assigned to

me.

Q Okay. Were there any assignments to you in 2007 under the CAPA?

A May have been. I don't recall.

Q If there were, they would be in your file?

A Will be in the CAPA file.

Q In the CAPA file. Did you keep a copy of the CAPA file in your file, your personal file?

A I don't know. I don't remember.

Q Where is CAPA, the CAPA file kept?

A With QA.

Q If you wanted to go look, where would it be kept?

A With QA.

Q In the QA department?

A Right.

Q That's Mr. Bitler's department; is that correct?

A In 2007, yes.

Q How about in 2008?

A In QA, I don't know where it was maintained right now. It may be quality

system, may be quality investigation group.

Q When's the last time you looked at the CAPA file?

A Again, you are asking the general question. I don't look into entire CAPA. I look -- I was informed on any particular incidence or assignment was given to my department, and I was responsible only for that particular incidence.

Q And what I'm asking you, sir, is when the last time is that you recollect looking at any part of the CAPA yourself.

A Yeah. If that particular incidence leads to my department, my action, I will look into that.

Q When is the last time you remember doing that, sir?

A I don't know exact date, but maybe last week could have been.

Q So it's a regular occurrence?

A It's a regular occurrence. We have due dates and we need to complete our actions, and we need to report to our QA department.

Q And that's usually within 30 days?

A Right.
Q Or you try to have it within 30 days?
A Yes. If not, we justify for extension and QA has to approve that extension.
Q Sir, in regard to the -- I want to get back to the QSIP plan that we were discussing. And you told me that the second plan started after May of two thousand -- in around May of 2008 or after May 20th of 2008. Who was in charge of that, or who is in charge of that?
A Quality system.
Q And is there any particular person that's in charge of the QSIP plan?
A I don't know who is particularly handling it, but director of quality system is Paul Galea.
Q And do you attend meetings relating to the QSIP post May 2008?
A I attended at the end of 2008. Wait. I attended some QSIP meeting from end of 2009, not 2008.

Q So do they still have regular weekly meetings?
A QSIP is a biweekly meeting, every two weeks.
Q And do you typically attend the biweekly meetings?
A Since end of 2009, sometime in August, September.
Q And the other plan that you told me about -- and I'm sorry. I'm having trouble looking at my notes. The one that you told me Mr. Talbot was in charge of --
A Quality improvement plan.
Q Quality improvement plan. Thank you, sir. The quality improvement plan, did it stop when Mr. Talbot left the company?
A That's right.
Q And when was that, sir?
A Talbot left December of 2007.
Q And did anyone take up continuing the quality improvement plan, to your knowledge?
A I have no idea.
Q You don't have any involvement in

that?

A No, no.

Q Do you keep a copy of that in your files, sir?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: I don't know.

BY MS. SANFORD:

Q When's the last time you recall looking at the quality -- any part of the quality improvement plan?

A I don't remember.

Q Before or after Mr. Talbot left the company? If you know.

A The quality improvement plan is the harmonization of our practice and procedure in different sites.

Q Right. I understand that, sir.

A Right.

Q I'm just asking when's the last time you remember looking at that, any portion of that plan.

A I think after Scott Talbot left, then I never heard of that particular program.

Q Okay. So it would have been prior to his leaving?
A Right.
Q Can you tell the jury, sir, in quality control and analytical services, from April 2007 to about April of 2008, what did it mean to release a product from your department, sir?
A From April of 2007 to April of 2008?
Q Yeah.
A The response of analytical services? That's what you're asking?
Q In your department, sir. The entire time in your department, can you tell the jury in your department in that time frame, April of 2007 through the end of April 2008, what did it mean for a product to be released from your department?
A From quality control laboratory?
MR. ANDERTON: Objection.
BY MS. SANFORD:
Q That's fine. We'll start there.
MR. ANDERTON: Objection.
You may answer.

THE WITNESS: In quality control laboratory, we test the product as per procedure and report our results and report all those results to quality assurance.

BY MS. SANFORD:

Q So when you see documents that reference a product being released or a lot or batch being released from your department, that's what it means?

A That's what it means.

Q You've released it to quality assurance?

A Quality assurance.

Q And that was true in 2007?

A That's right.

Q Was it true up to the time you left that position in 2008?

A That's right.

Q Who was in charge of quality assurance in November of 2007?

A November 2007?

Q Yes.

A Dan Bitler.

Q Was that true in December of 2007 as well?
A Yes.
Q And January of 2007?
A Yes.
Q Did Mr. Bitler ever contact you about any of the products or results that you released to his department?
A No. We turned over the entire document, the laboratory document, to QA.
Q Is there ever any time that you can remember, sir, that his department, that's quality assurance, rejected a product you had released?
MR. ANDERTON: Objection.
You may answer.
THE WITNESS: He may have. I don't have any recall.
BY MS. SANFORD:
Q As head of the department, it would probably be something that would be brought to your attention, I assume, sir?
A Not necessarily.
Q What happens if they reject -- if a

product has been released from your lab that's been rejected by quality assurance? Walk me through the process there.

MR. ANDERTON: Objection.

THE WITNESS: He will reject --

MR. ANDERTON: Wait.

Objection; mischaracterizes his testimony.

You may answer.

THE WITNESS: He will reject the particular product.

BY MS. SANFORD:

Q What would be the reasons he would reject it, sir?

A He may have a number of other reasons. We just provide that one particular part of the puzzle. We just give the laboratory test results. He reviewed the manufacturing document. He reviews the packaging document. He reviews everything, all the documents and all the events. Then he make the decision whether to accept or reject the product.

Q So a drug product that's been

released from your department, sir, goes to quality assurance. Quality assurance then does the packaging on the product?

A Packaging --

MR. ANDERTON: Objection. Again, mischaracterizes his testimony.

You may answer.

THE WITNESS: Packaging, package department. Packaging department package the product, not quality assurance.

BY MS. SANFORD:

Q So what does quality assurance do once it's released from you on a product?

MR. ANDERTON: Objection.

You may answer.

THE WITNESS: They wait for other documents to come in. They review all the documents. Then they determine whether product can be released or rejected.

BY MS. SANFORD:

Q And, sir, in 2007, in November and December of 2007, do you know how many people

were working in the quality assurance department?

A I don't know.

Q And as you sit here today, you can't recall any specific product at any time that was rejected by quality assurance that was brought to your attention?

A That's right.

Q Sir, can you tell the jury the difference between a batch and a lot? I'm on a new subject, so I don't want to confuse you with that.

A Lot usually refer to raw material situation, and batch is a finished product batch. It's intermittently -- sometimes people use lot and batch number.

Q But in your mind, in your department, batch would refer to a finished product?

A That's right.

Q And lot would refer to raw materials?

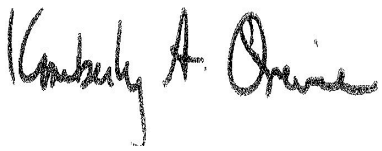
A That's correct.

Q So when a product goes out with a

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, SWAPAN ROYCHOWDHURY, have the opportunity to read and sign the deposition transcript.



KIMBERLY A. OVERWISE
Certified Realtime Reporter
Notary Public
Dated: December 31, 2009

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Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

ACKNOWLEDGMENT OF DEPONENT

I, SWAPAN ROYCHOWDHURY, do hereby certify that I have read the foregoing pages, 1-355, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____ _____

SWAPAN ROYCHOWDHURY DATE

Subscribed and sworn
to before me this
____ day of _____, 2009.

My commission expires:_____

_____
Notary Public